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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/820,144 | 04/08/2004 | Esther H. Chang | 2444-116 | 6653 |
| 6449 | 7590 | 05/10/2006 | EXAMINER | |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005 | | | CHEN, SHIN LIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,144

Applicant(s)

CHANG ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,22,23,25-29 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20,22,23,25-29 and 32-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, 32 and 36, drawn to a vector for delivery of a virus to a target cell within a host animal consisting essentially of a cell-targeting ligand, which is a protein, peptide or hormone, non-covalently bound to said virus, wherein said ligand binds directly to a receptor on said target cell, and a method for preparing said vector, classified in classes 435 and 530, subclasses 320.1 and 350, respectively.
 - II. Claims 1-9, 13-18 and 33-35, drawn to a vector for delivery of a virus to a target cell within a host animal consisting essentially of a cell-targeting ligand, which is an antibody or antibody fragment, non-covalently bound to said virus, wherein said ligand binds directly to a receptor on said target cell, and a method for preparing said vector, classified in classes 435 and 424, subclasses 320.1 and 130.1, respectively.
 - III. Claims 19, 20, 22, 23, 25-29, 37 and 38, drawn to a method for targeting delivery of a nucleic acid to cancer cells of an animal comprising administering systemically to said animal a viral vector consisting essentially of a virus comprising said nucleic acid and a cell-targeting ligand, which is a protein, peptide or hormone, non-covalently bound to said virus and binds directly to a receptor on said cells, classified in classes 514 and 530, subclasses 44 and 350, respectively.
 - IV. Claims 19, 20, 22, 23, 25, 27, 28, 37 and 38, drawn to a method for targeting delivery of a nucleic acid to cancer cells of an animal comprising administering

systemically to said animal a viral vector consisting essentially of a virus comprising said nucleic acid and a cell-targeting ligand, which is an antibody or antibody fragment, non-covalently bound to said virus and binds directly to a receptor on said cells, classified in classes 514 and 424, subclasses 44 and 130.1, respectively.

- V. Claims 25, 26, 29 and 39-44, drawn to a method of specifically targeting and sensitizing cancer cells to radiation or chemotherapy comprising administering systemically or intratumorally to a person a viral vector consisting essentially of a virus comprising a nucleic acid that will sensitize said target cells and a cell-targeting ligand, which is a protein, peptide or hormone, non-covalently bound to said virus and binds directly to a receptor on cancer cells, classified in classes 514 and 530, subclasses 44 and 350, respectively.
- VI. Claims 25 and 39-44, drawn to a method of specifically targeting and sensitizing cancer cells to radiation or chemotherapy, a method of increasing level of expression of a nucleic acid in target cancer cells, and a method of administering a chemotherapeutic or radiation therapy agent to an animal comprising administering systemically or intratumorally to a person a viral vector consisting essentially of a virus comprising a nucleic acid that will sensitize said target cells and a cell-targeting ligand, which is an antibody or antibody fragment, non-covalently bound to said virus and binds directly to a receptor on cancer cells, classified in classes 514 and 424, subclasses 44 and 130.1, respectively.

Claims 1-9 and 13-18 link(s) inventions I-II. Claims 19, 20, 22, 23, 27, 28, 37 and 38 link(s) inventions III-IV. Claim 25 link(s) inventions III-VI. Claims 26 and 29 link(s) inventions III and V. Claims 39-44 link(s) inventions V-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-9, 13-20, 22, 23, 25-29 and 37-44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions: proteins, peptides, and hormones vs. antibodies and antibody fragments. A search for protein, peptide, or hormone does not require a search for antibody or antibody fragment, and vice versa. Further, groups I and II are drawn to materially different methods that differ at least in method steps, reagents and doses used, schedules used, response variables, and criteria of success. They

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have different classifications and require separate search. Thus, groups I and II are not obvious variants and are patentably distinct from each other. Similarly, groups III and IV are patentably distinct from each other for the same reason. Groups V and VI are patentably distinct from each other for the same reason.

Groups I-II, groups III-IV and groups V-VI are patentably distinct from each other because they are drawn to different scientific considerations: a method for preparing a vector, a method for targeting delivery of a nucleic acid to cancer cells of an animal, and a method of specifically targeting and sensitizing cancer cells to radiation or chemotherapy. They have different design and different mode of operation. They are drawn to methods that differ at least in objectives, method steps, reagents and doses used, schedules used, response variables, and criteria of success. They have different classifications and require separate search. Thus, groups I-II, groups III-IV and groups V-VI are not obvious variants and are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



SHIN-LIN CHEN
PRIMARY EXAMINER